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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,155	10/20/2005	Ludovic Predal	4092-001	7738

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AXINN, VELTROP & HARKRIDER LLP
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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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08/21/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@AVHLAW.COM

Office Action Summary	Application No. 10/554,155	Applicant(s) PREDAL, LUDOVIC	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's Request for Continued Examination, amendment, response and IDS filed June 11, 2009 have been received and entered into the case. Claims 1, 3 – 14, 17 – 19 and 20 – 27 are canceled; claims 28 – 41 are added; claims 28 – 41 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 30, 32 – 33 and 39 - 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is indefinite for not first spelling out full terms followed by their abbreviation in parenthesis. Specifically the terms "BHA" and "TBA".

Claims 32 – 33 are rendered vague and indefinite as they are not independent claims and do not recite the claim on which they depend. For purposes of examination, the claims have been interpreted to depend from claim 28.

Claims 39 – 41 are indefinite as they depend from a canceled claim. For purposes of examination, the claims have been interpreted to depend from claim 28.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 28 – 31, 34 – 38 and 40 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeMichele et al. (US 5223285).

DeMichele teaches pharmaceutical compositions comprising ALA, EPA, DHA, vitamin E and gamma LA (abstract).

The reference does not teach the compositions with the claimed amounts of each component. However in following the general tone of the reference, it would have been obvious to one of ordinary skill in the art to optimize the various amounts of each component as they are all identified as active components, or result effective variables. Thus, at the time of the claimed invention one of ordinary skill in the art would have been motivated by the cited reference to optimize the amounts of the various components with a reasonable expectation for successfully obtaining an effective pharmaceutical composition. Regarding the limitations to the way in which it is stored (claims 40 - 41), it is noted that these limitations are not drawn to the composition itself and do not patentably distinguish over the prior art compositions.

5. Claims 28 – 38 and 40 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbruzzese et al. (US 6077828).

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Abbruzzese teaches pharmaceutical compositions comprising ALA, EPA, DHA, vitamin E (abstract) and gamma LA (col.5) wherein the composition may be a capsule (col.4 line 30-55)

The reference does not teach the compositions with the claimed amounts of each component. However in following the general tone of the reference, it would have been obvious to one of ordinary skill in the art to optimize the various amounts of each component as they are all identified as active components, or result effective variables. Thus, at the time of the claimed invention one of ordinary skill in the art would have been motivated by the cited reference to optimize the amounts of the various components with a reasonable expectation for successfully obtaining an effective pharmaceutical composition. Regarding the limitations to the way in which it is stored (claims 40 - 41), it is noted that these limitations are not drawn to the composition itself and do not patentably distinguish over the prior art compositions.

6. Claims 39 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeMichele et al. or Abbruzzese et al. in view of Sundram et al. (US 2002/0034562) or Makadia et al. (US 2006/0111254).

DeMichele teaches pharmaceutical compositions comprising ALA, EPA, DHA, vitamin E and gamma LA (abstract).

Abbruzzese teaches pharmaceutical compositions comprising ALA, EPA, DHA, vitamin E (abstract) and gamma LA (col.5) wherein the composition may be a capsule (col.4 line 30-55)

The references do not teach the compositions with the claimed amounts of each component or the claimed form of powder or granule. However in following the general tone of the references, it would have been obvious to one of ordinary skill in the art to optimize the

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various amounts of each component as they are all identified as active components, or result effective variables. Thus, at the time of the claimed invention one of ordinary skill in the art would have been motivated by the cited reference to optimize the amounts of the various components with a reasonable expectation for successfully obtaining an effective pharmaceutical composition.

The references do not teach the compositions as a powder or granule. However in following the general tone of the references, it would have been obvious to one of ordinary skill in the art to optimize the forms of the composition as it was routine in the art to do so as a matter of routine experimentation.

The references do not teach the compositions stored in a colored or tinted containers/capsules. However, at the time of the claimed invention, such fatty acid/oil compositions were well known to typically be stored in dark or opaque containers to reduce oxidation of the composition. In support, Sundram teaches storing oil compositions in dark storage containers to exclude light (0098) while Makadia teaches storing oils in opaque containers to reduce oxidation (0098). Thus, as evidenced by the cited references, it would have been obvious to one of ordinary skill in the art to store the fatty acid/oil compositions of DeMichele and/or Abbruzzese in a dark/opaque/tinted/colored container as it was routine in the art to do so in order to protect the compositions, and with a reasonable expectation for successfully storing the compositions of DeMichele and/or Abbruzzese.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner, Art Unit 1651

August 13, 2009.